

## **REMARKS**

### **Pending Claims**

Claims 16-24 have been canceled with traverse in view of the prior Restriction Requirement. Applicant reserves the right to file a divisional application to the canceled subject matter. Claims 5-9, and 11-13 have been canceled. Language from those claims now appears in new claims 25-30. The new claims have been added merely as a convenience to the Office and should not be construed as a response to an issue of patentability.

Support for the new claims can be found throughout the instant specification including the Drawings and claims as filed originally.

Particular support for claims 25-30 can be found in claims 4, 5, 6, 7, 14, and 15 (respectively) as written originally and in the sequence listing.

In particular, support for "BSP<sup>II</sup>" as a preferred bone sialoprotein gene in new claim 25 can be found, for instance, at pg. 6, lines 15-25.

Specific support for the sequences featured in new claims 25, 26, and 27, can be found in Figure 1, for instance, as well as elsewhere in the case.

No new matter has been added by virtue of the new claims.

Applicant now responds to the Action.

As an initial matter, Applicant gratefully acknowledges the Examiner's reconsideration of

the restriction requirement insofar as the two sialoprotein gene polymorphisms are being considered in this case. See ¶ 2 at pg. 4 of the Action.

At ¶ 3 of the Action, the Office took the position that claims 5-9 and 11-13 would be withdrawn from consideration on grounds that a non-elected invention was encompassed. Applicant respectfully disagrees with that position. Embodiments of the canceled claims now appear in new claims 26-28, for instance. This language is proper, since new claims 25-30 depend from new claim 24 which features the presently elected BSP polymorphism.

**35 USC §112, second paragraph**

Claim 1 stands rejected as indefinite on grounds that "it is not clear how the single recited method step accomplishes the goal set forth in the preamble of the claim." Action at pg. 5, ¶6. While Applicant respectfully disagrees claim 1 (now canceled) is at all unclear, the claim has been redrafted as new claim 25. It is submitted that the new claim would be clear and unambiguous to one working in this field. In particular, new claim 25 features specific determination and association steps that point out the intended method with ample precession. Some of this language appears in claim 10 (now canceled).

At ¶6 of the Action on pgs. 5-6, bridging paragraph, the Office also alleged that Claim 1 was unclear for reciting "bone sialoprotein gene". While Applicant must respectfully disagree that the phrase would at all be unclear to one working in this field who read the instant application, the phrase has been used with more particularity in new claim 25. That is, the new claim features a more specific bone sialoprotein gene ie., BSP<sup>II</sup>.

On pg. 6 of the Action, claim 2 was alleged to be indefinite. Although Applicant respectfully disagrees with the position taken, the rejection is moot in view of the present submission.

Also on pg. 6, the Office contended that claim 4 was indefinite in view of particular sequence references. More specifically, the Office alleged that:

The claim is indefinite [over this recitation] because, first, the allelic identifier are arbitrary identifiers whose definition is not clear from the specification as the numbering system referred to in the specification is **not a fixed numbering system**.... [r]eliance upon a Genbank record does not provide adequate clarity for the claimed invention, as **the content and numbering in a GenBank record can change over time as the records can be updated as time passes**.

As an initial matter, the undersigned notes that 35 USC §112 speaks as of the application filing date. As the Federal Circuit has explained, it is legal error to rely on subsequent developments in a field to find uncertainty as to terms used in a patent. See W.L. Gore & Associates, Inc. v. Garlock, Inc. 721 F.2d 1540, 220, USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Were the legal standard otherwise, inventors would be charged with the onerous task of having to update their applications as developments in the field or the USPTO dictated. In contrast to the position taken by the Office in this case, the Federal Circuit simply does not require one seeking a patent to do this. See W.L. Gore & Associates, Inc. v. Garlock, Inc., *ibid*.

Mindful that §112 speaks to the issue of claim clarity when a case is filed, the Office has the burden of showing that a skilled worker reading the instant case would find the claims ambiguous. That burden has not been met. No evidence has been presented that the worker would not know what was meant by the disclosed sequence identifiers and references to the Genbank numbering system as of the filing date. Whether or not Genbank's numbering system is fixed or unfixed for a particular sequence is simply not germane to the Office's inquiry under 35 USC §112, second paragraph. It is submitted that at the time the instant case was filed, one of skill readily understood what was meant

by the identifiers and could access Genbank to confirm and study them if needed. No contrary evidence has been presented by the USPTO.

In view of the legal standard set forth above, reference to a Genbank accession number as of the filing date of a patent application, without more, is not ambiguous *per se* within the meaning of §112.

However, even if we assume, *arguendo*, that a particular Genbank record did change after Applicant's filing date, it is submitted that Genbank (a world-renowned depository of genetic information supported the U.S. government) would provide sufficient information to allow the worker to identify prior records. Thus if a particular Genbank record changed, one of skill could readily learn what change occurred and could identify related sequence identifiers and Genbank references. No contrary evidence has been presented by the Office.

Turning to new claims 25-27, it is submitted that the featured sequences, sequence ID nos. and Genbank references would be abundantly clear in view of the specification and particularly Figure. 1. Thus it is submitted that the specification amendments referred to on pg. 7 of the Action are not required as they relate to these claims.

With respect to new claim 28, Applicant has taken sequence from Genbank accession no. AB008821 (disclosed at pgs. 6-7, bridging paragraph, of the instant application, for instance). Although Applicant believes the claim is quite clear as written, he will submit a Rule 132 Declaration stating, among other things, that the featured sequence information was available to him as accession no. AB008821 as of the application filing date.

The Office had further basis for rejecting the claim that concerned use of the SEQ

ID Nos. in the claims (all wild type sequences). The new claims feature both the wild type and varied sequence (referencing appropriate SEQ ID Nos) to improve claim clarity.

At the bottom of pg. 7 of the Action, claim 10 was rejected on grounds that "lower peak bone mass" was indefinite. Although Applicant respectfully disagrees, new claim 25 addresses the issue.

In view thereof, reconsideration and withdrawal of the rejections are requested.

**35 USC §112, first paragraph**

Claims 1, 2, 3, 14 and 15 stand rejected as not being sufficiently described by the application as filed. While Applicant respectfully disagrees with the position as taken, the rejection is moot in view of this submission.

Moreover, it is not believed that the rejection applies to the new claims. For instance, new claim 25 has been written along lines of canceled claim 4. As formulated, the rejection did not encompass claim 4.

Additionally, the Office position regarding "breadth of the claims" on pg. 11 is moot in view of this submission. Likewise, the rejection based on other polymorphisms is also moot.

Accordingly, reconsideration and withdrawal of the rejection are requested.

**35 USC §102**

Claims 1, 2, and 14 stand rejected as anticipated over Kim et al. (*Matrix Biology*, Vol. 14/1994, pg. 31-40). Applicants respectfully disagree with the rejection as formulated. However, the rejection is fully addressed by this submission. In particular, the claims have been canceled.

Moreover, new independent claim 25 is written along lines of claim 4 (now canceled). Accordingly, there is no basis for maintaining the rejection.

Applicant also disagrees with the rejection as follows.

As cited, Kim et al provides for a method that includes determining the genotype of the promoter of the BSP gene and discloses a sequence for that gene. However as relied on by the Office, there is no particular discussion in the reference regarding the effect of any allelic variation on bone mass. New claim 25 addresses this concern, for instance, by reciting a step of associating the presence of particular stated allelic variations with consequences in terms of a predisposition to a lower peak bone mass. Accordingly, all the new claims are novel over the reference as used in the rejection.

In view thereof, Applicant requests reconsideration and withdrawal of the rejection.

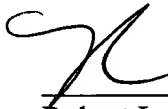
### **CONCLUSION**

Applicants submit that all claims are allowable as written and respectfully request early favorable action by the Examiner. If the Examiner believes that a telephone conversation with Applicants' attorney would expedite prosecution of this application, the Examiner is cordially invited to call the undersigned attorney of record.

Although it is not believed that any further fee is needed to consider this submission, the Office is hereby authorized to charge our deposit account 04-1105 should such fee be deemed necessary.

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Respectfully submitted,



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